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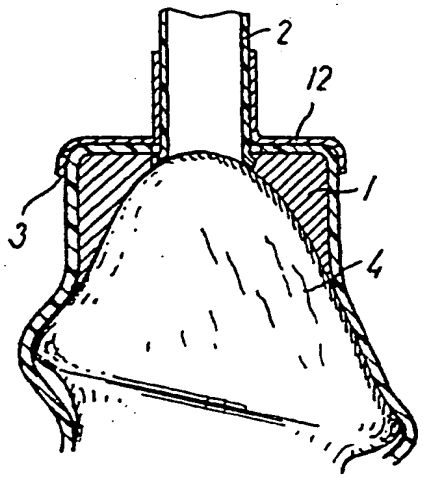
(54) Title: EXTERNAL URINARY CATHETER



(57) Abstract

An external urinary catheter for the relief of male urinary incontinence comprises a catheter member (1) to be placed under the foreskin (3) in abutment with the head (glans) (4) of penis. The catheter member (1) has such a short axial length that in use it only covers the extreme portion of glans (4) outside the point where glans has its largest diameter, and in the area of the transition to the discharge spout (2) is designed with such a form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

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External urinary catheter.

The invention relates to an external urinary catheter for the relief of male urinary incontinence and of the kind which in connection with a discharge spout for connection with a hose comprises a catheter member having such a short axial extent, that in use it is placed in abutment with the head (glans) of penis and only covers the extreme portion of glans outside the point where glans has its largest diameter.

For the relief of male urinary incontinence external catheters are generally used in the form of condomlike tubular sheaths to be placed externally on penis and having a discharge spout which via a hose is connected with a urine collection bag.

Such external catheters are known in numerous designs and in many cases serve as a satisfactory solution of male incontinence problems. The complete envelopment of penis may, however, give rise to troubles, partly because the application which is effected by unrolling the catheter requires a certain length of penis, partly in use due to the fact that the envelopment of the full length of penis with the catheter which is generally fastened adhesively either by means of a separate adhesive strip or by means of an internal adhesive layer involves strain of the skin and the constantly humid environment from the delivered urine entail skin problems, such as allergy and maceration and in worst case ulceration.

The application problem entails that conventional external catheters cannot be used by incontinence patients having a too small or retracted penis.

Published patent application GB-A-2075847 proposes an external male urinary catheter in the form of a relatively short funnel-like uridom device which is placed

directly against glans penis throughout its length, but nevertheless envelops glans and is kept in place under the foreskin. Around a discharge spout of the device an external sheath is fastened which after the application of the catheter is brought in abutment with the outer side of the foreskin so that the whole device is kept in place by the position of the foreskin between the inner catheter element and the external sheath.

As conventional catheters of the above-mentioned kind said prior art urinary catheter requires a relatively accurate adaptation to the anatomy of the user and must thus, inter alia, be manufactured in various sizes. The manufacturing which may be effected by injection moulding is further complicated by the integrated design of the inner catheter member and the outer holder member. The complete envelopment of glans penis with the catheter member, whereby the proximal end edge thereof which is provided with a bead is placed against the relatively sensitive skin band between glans and foreskin may in use give rise to considerable nuisance. Furthermore, the fixation principle entails the risk that the catheter might fall off in use in the case of a pull, e.g. from the collection bag connected with the discharge spout, or compressive load in connection with the urination.

US Patent No. 4640688 discloses a catheter member of the above-mentioned kind having such a short axial extent that in use it only covers the extreme portion of glans to which it is fastened by means of an adhesive which in a manner known per se may be applied in the form of a coating on the inner side of a cup-shaped part of the catheter. The need for an adhesive connection makes such a catheter unpleasant in use, because the above problems with skin strain have not been eliminated.

On the basis of said prior art it is the object of the invention to provide an external urinary catheter which through a further development of the fastening concept explained in the above GB patent application entails an easier application and improved use properties as regards reduced inconveniences in fastening the inner catheter member about the mouth of urethra. It is further an object to provide a product design which is more simple to manufacture.

The urinary catheter according to the invention is for this purpose characterized in that the catheter member in its state of use is intended to be placed under the foreskin for fastening this without adhesive connection with glans, as the catheter member in the area at the transition to the discharge spout is formed with such a form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

In relation to conventional uridoms the catheter according to the invention entails the advantage that the risk of allergic problems and skin strain is considerably reduced because the skin contact is restricted to the extreme portion of glans and the foreskin, and because no adhesive fastening is used.

Likewise the application is simpler because the catheter does not need to be unrolled, and the possibilities of use of the catheter are thus also less dependent on the size of penis.

In relation to the prior art catheter according to above GB patent application there is first and foremost obtained a substantially less disturbing position without the risk of tissue damage as a result of that only the extreme portion of glans is covered by the inner catheter member.

Thereby, the possibility is further obtained that the catheter according to the invention may be manufactured as a "one-size" product, which considerably reduces the cost of storage and thus makes the production less expensive.

The improved form stability in the area at the transition to the discharge spout entails that the catheter member through a suitable outer shape may be produced with a sufficient security against falling off in use due to a pull or compressive load.

This advantage is particularly obtained by a preferred embodiment, in which the catheter further comprises an outer holder member for fastening the catheter member in the state of use, and which is characterized in that the outer holder member is a separate member enveloping the discharge spout of the inner catheter member, and may be displaced axially in relation thereto.

The separate outer holder member placed on the discharge spout is after arrangement of the catheter member under the foreskin pressed to abut on the outer side of the extreme part of the foreskin. This provides for obtaining a particularly reliable fastening with no substantial inconveniences to the user, since a load in the form of a pull at the discharge spout, e.g. due to the weight of the urine collection bag connected with the discharge spout, or a compressive load from the urine instead of involving the risk that the catheter falls off, entails an improvement of the fastening of the foreskin between the catheter member and the outer holder member.

The invention will now be explained in detail with reference to the schematical drawings, in which

Figs. 1 and 2 show a sectional view of a preferred embodiment of the catheter according to the invention, with and without the outer holder member, respectively,

Fig. 3 the catheter shown in Fig. 1 in an applied condition, and

Figs. 4 to 8 show differently modified designs.

The example shown in Fig. 1 of an external urinary catheter according to the invention comprises an inner catheter member 1 and a tubular discharge spout 2 intended for connection of the catheter with a hose, not shown, leading to a urine collection bag that may be of a known design.

The catheter member 1 and the discharge spout 2 are manufactured in one piece, e.g. by injection moulding of thermoplastic elastomeric material.

The catheter member 1, which as shown in Fig. 2 in the state of use is intended to be placed under the foreskin 3 in contact with the head or glans 4 of penis, has according to the invention such a short axial extent, e.g. 5 to 35 mm, that in use it only covers the extreme portion of glans outside the point where glans has its largest diameter.

It is thereby prevented, that the catheter member 1 in the state of use is placed with its end edge 5 against the sensitive skin band between glans and foreskin.

At the transition to the discharge spout 2 the in itself elastically resilient catheter element 1 is designed with such a form stability that in use it preserves its outer shape at the place where the catheter member is fastened by the extreme portion of the foreskin 3.

In the embodiment in Fig. 1 to 3 the increased form stability at the transition between the catheter member 1 and the discharge spout 2 is obtained in a simple

manner in that the catheter member 1 is designed with an increased wall thickness in this local area.

The illustrated catheter member 1 is thus designed with an almost bowl-shaped profile, where a substantially plane outer surface 6 is provided about the discharge spout 2 substantially perpendicular to the discharge spout 2, whereas the side wall of the bowl-shaped profile is formed by a skirt portion 7, which joins the outer surface 6 via a shoulder-like ledge 8.

The internal side of the catheter member 1 constitutes an arched bowl-shaped bottom face 9 fitting to the shape of the extreme portion of glans 4.

The application is effected in that the catheter member 1 with the foreskin 3 retracted is placed against glans 4, the discharge spout being placed opposite the mouth of urethra, after which the foreskin 3 is passed out and around the catheter member 1 and fastens this in that the slightly stretched foreskin presses against the outer surface 6.

Practical tests have shown that by virtue of the elasticity of the foreskin 3 in itself and the increased form stability at the transition between the catheter member 1 and the discharge spout 2 a surprisingly good fastening of the catheter member 1 is obtained in the state of use, even with no further arrangements.

Thus, inter alia patients confined to bed can often make use of the catheter with sufficient security without the separate holder member that will be described in the following.

Even though the catheter member 1 as already mentioned in many cases can be used alone an outer holder member 10 may be used to obtain an additionally secure fastening, said member being manufactured as a separate member with a tubular part 11 enveloping the discharge spout 2 but not narrower than it can be dis-

placed axially thereon, possibly in connection with a backstop in the discharge spout.

In connection with the spout-shaped part 11 the holder member 10 in the embodiment in Figs. 1 and 2 has a substantially bowl-shaped profile 12 having a substantially uniform wall thickness.

The holder member 10 may like the catheter member 1 be manufactured by injection moulding of a thermoplastic elastomer.

Upon application, after that the catheter member 1 has been placed against glans 4 in the above described manner the holder member 10 is pressed against the outside of the foreskin 3 after this has been passed up around the catheter member 1.

The design of the holder member 10 so that it may be displaced on the discharge spout 2 entails the advantage that in case of a tensile load on the discharge spout 2, e.g. due to the weight of the urine collection bag in use only a pull in the catheter member will be exerted, since the tensile load causes an elastic extension and thus a somewhat smaller diameter of the discharge spout 2, whereas the holder member 10 is less affected. The tensile load will thus entail an increased squeeze effect on the extreme portion of the foreskin 3.

The fastening principle may thus in a way be said to be load compensating.

Figs. 4 to 8 show various alternative designs.

In Fig. 4 the catheter member 13 and the holder member 14 are both formed with a bowl-shaped cross-section having a substantially uniform wall thickness. The enhanced form stability at the transition between the catheter member 13 and the discharge spout 15 is here obtained in that the catheter member 13 is provided

with one or more circumferential ribs 16 on the outer side.

In the embodiment in Fig. 5, in which the catheter member 17 and the holder member 18 have almost the same cross-sectional shape as in Figs. 1 and 2 the catheter member is at its proximal end edge provided with an inwards extending, relatively soft sealing lip 19 which is particularly suited to give an improved sealing in case of more severe incontinence.

In the embodiment in Fig. 6 the catheter member 20 is provided with a raised shoulder portion 21 at the transition to the discharge spout 22 and the cross-sectional shape of the holder member 23 is designed with a corresponding profile to obtain an additionally improved form stability and fastening ability.

In the embodiment in Fig. 7, in which the catheter member 24 substantially is designed as shown in Figs. 1 and 2, the outer holder member 25 is designed as a relatively thin collar portion having a plane underside 26. It is thus not necessary that the holder member extends beyond and envelops the shoulder-like ledge on the catheter member.

Finally, Fig. 8 shows an embodiment, in which the catheter member 27 and the holder member 28 in principle are designed in the same manner as shown in Fig. 3 but in which the increased form stability at the transition to the discharge spout 29 is obtained by an embedded reinforcing or stiffening ring 30 which may be of an appropriate plastic material, e.g. polypropylene.

PATENT CLAIMS

1. An external urinary catheter for the relief of male urinary incontinence and of the kind which in connection with a discharge spout (2) for connection with a hose comprises a catheter member (1) having such a short axial extent, that in use it is placed in abutment with the head (glans) (4) of penis and only covers the extreme portion of glans (4) outside the point where glans has its largest diameter, characterized in that the catheter member (1) in its state of use is intended to be placed under the foreskin (3) for fastening this without adhesive connection with glans, said catheter member in the area at the transition to the discharge spout (2) being formed with such a form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

2. An external urinary catheter according to claim 1, characterized in that the catheter member (1) around the discharge spout (2) has a substantially plane abutment face (6) substantially perpendicular to the discharge spout, said abutment face joining a short skirt portion (7) via a shoulder-like ledge (8).

3. An external urinary catheter according to claim 1 or 2, characterized in that the catheter member (17) at its proximal end edge is provided with an inwards extending, relatively soft sealing lip (19).

4. An external urinary catheter according to claim 1, 2 or 3, characterized in that the catheter member (13) is provided with a circumferential rib (16) on the outer side.

5. An external urinary catheter according to any of the preceding claims, characterized in that the catheter member (27) is substantially bowl-shaped and is provided with an embedded circumferential stiffening ring (30).

6. An external urinary catheter according to one of the preceding claims and further comprising an outer holder member (10) for fastening the catheter member (1) in the state of use, characterized in that the outer holder member (10) is a separate member enveloping the discharge spout (2) of the inner catheter member, but may be displaced axially in relation thereto.

7. An external urinary catheter according to claim 6, characterized in that the outer holder member (26) is provided with an inner face adapted to the outer side of the catheter member (20).

8. An external urinary catheter according to claim 6 or 7, characterized in that the outer holder member (25) around the discharge spout is designed as a collar portion having a substantially plane underside (26).

9. An external urinary catheter according to claim 6, 7 or 8, characterized in that the outer holder member (10, 14, 28) is substantially bowl-shaped.

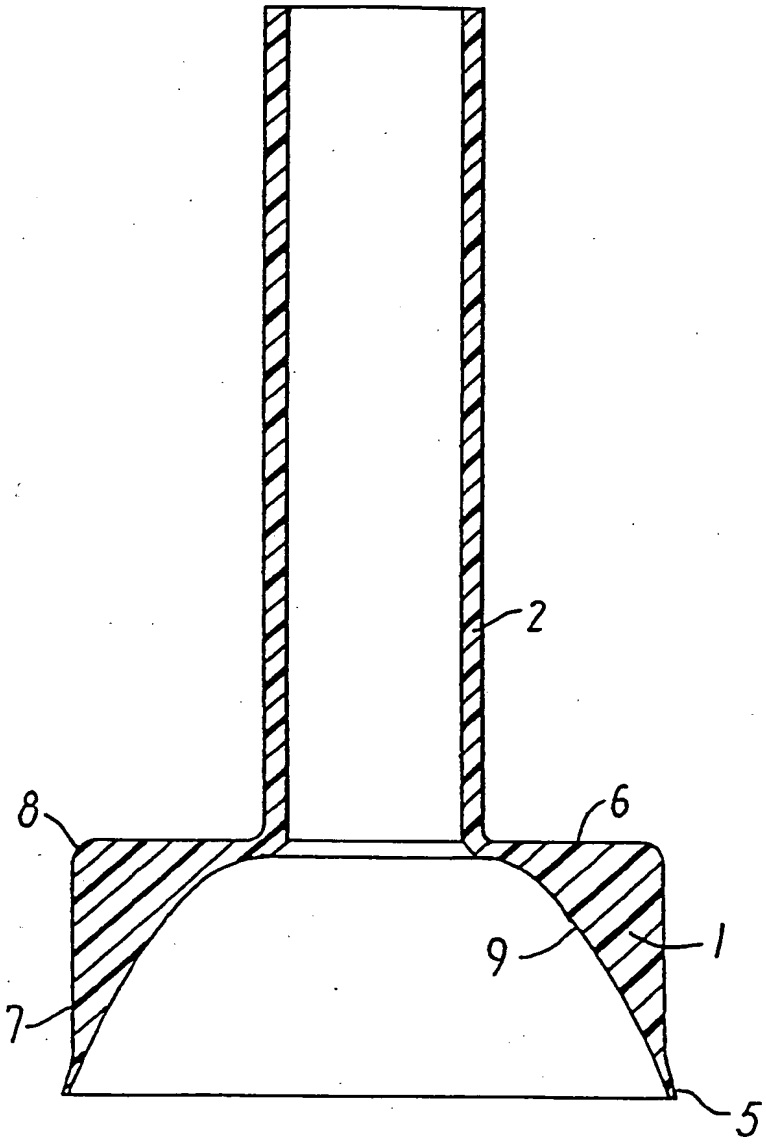

FIG. 1

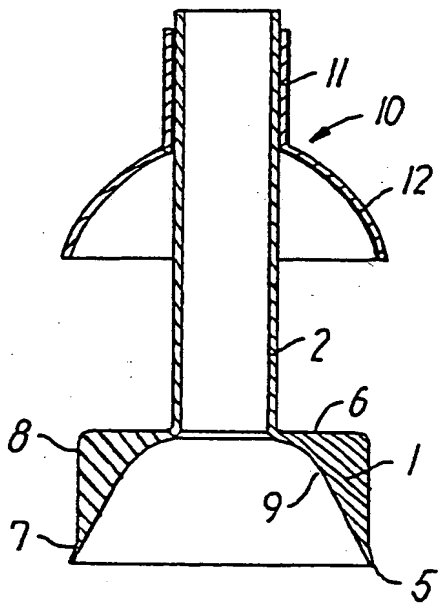

FIG. 2

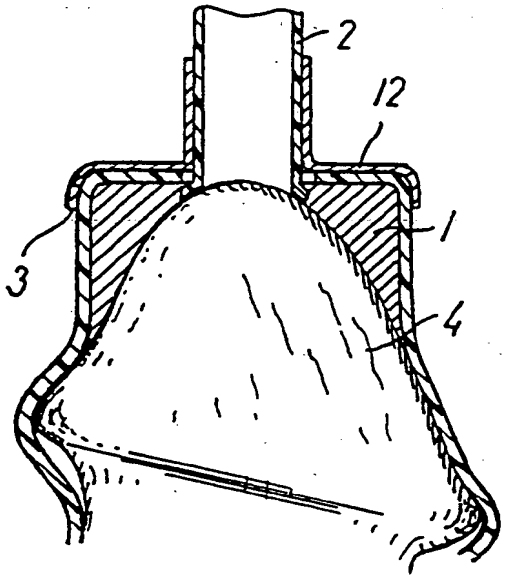

FIG. 3

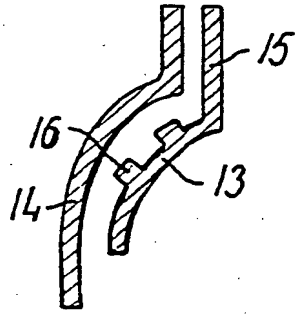

FIG. 4

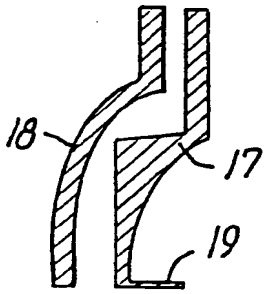

FIG. 5

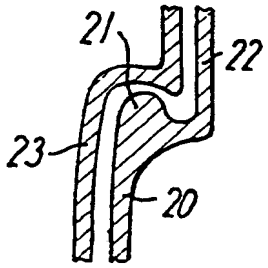

FIG. 6

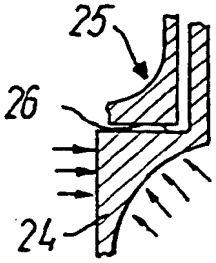

FIG. 7

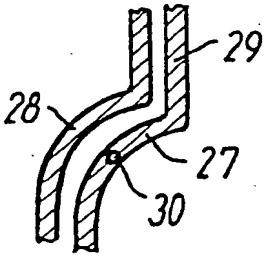

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 94/00267

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/453 // A 61 M 25/02
According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE, A, 520401 (OSKAR WENDT ET AL.), 19 February 1931 (19.02.31), figure 1	1,3,6,7,9
X	GB, A, 2126483 (WILLIAM RALPH COLEMAN IVENS ET AL.), 28 March 1984 (28.03.84), page 3, line 5 - line 62, figure 6	1-2,4-9
A	DE, A, 221533 (JOSEPH BARTECZKO), 30 April 1910 (30.04.10), figures 1a, 1b	1
A	US, A, 4388923 (KEN HEIMREID), 21 June 1983 (21.06.83)	1,4-7,9

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 October 1994	20 -10- 1994
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 94/00267

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4640688 (THOMAS M. HAUSER), 3 February 1987 (03.02.87), figure 1	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

01/10/94

International application No.
PCT/DK 94/00267

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-A- 520401	19/02/31	NONE		
GB-A- 2126483	28/03/84	NONE		
DE-A- 221533	30/04/10	NONE		
US-A- 4388923	21/06/83	AU-B-	544779	13/06/85
		AU-A-	7013681	19/11/81
		BE-A-	888768	28/08/81
		CA-A-	1160125	10/01/84
		DE-A-	3114894	16/06/82
		FR-A,B-	2482450	20/11/81
		GB-A,B-	2075847	25/11/81
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		JP-A-	57003635	09/01/82
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		NL-A-	8102075	01/12/81
		SE-B,C-	449432	04/05/87
		SE-A-	8102808	14/11/81
		SU-A-	1127523	30/11/84
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		JP-A-	62090172	24/04/87

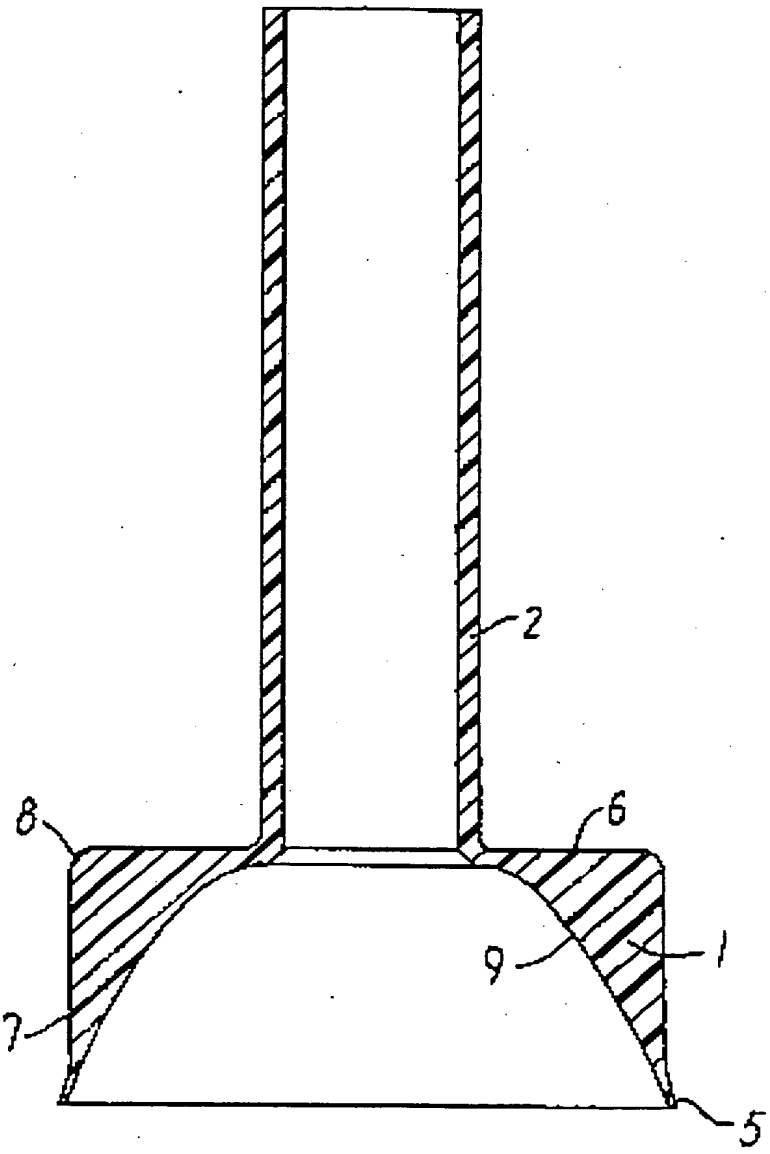

FIG. 1

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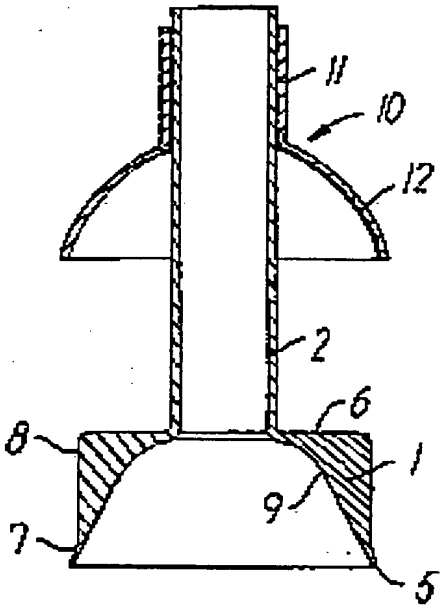

FIG. 2

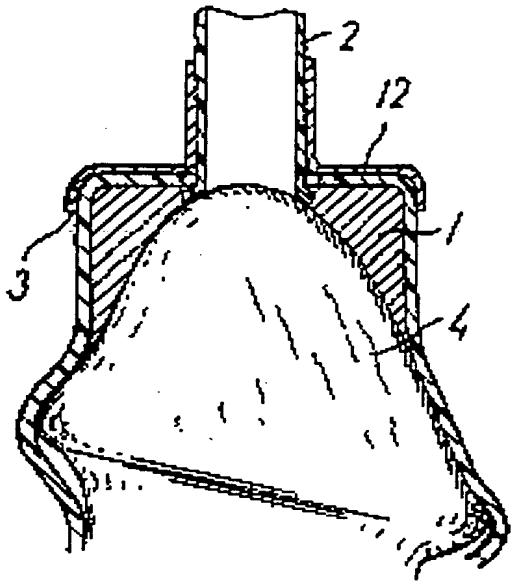

FIG. 3

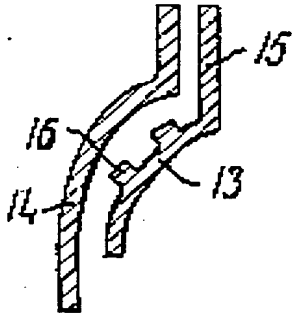

FIG. 4

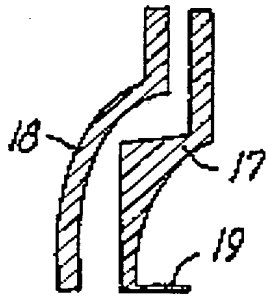

FIG. 5

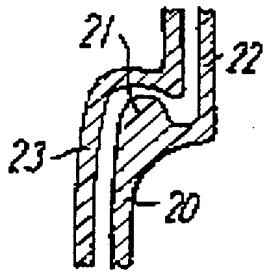

FIG. 6

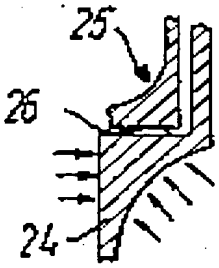

FIG. 7

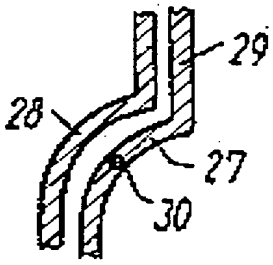

FIG. 8